

June 1, 2004

Reply to Office Action of December 1, 2003

**REMARKS**

Claims 1 and 3-9 presently appear in this case. No claims have been allowed. The official action of December 1, 2003, has now been carefully studied. Reconsideration and allowance are hereby respectfully urged.

Briefly, the present invention relates to a recombinant DNA molecule including a specified amino acid sequence, which polypeptide has the ability to interact with TNF in such a manner as to inhibit the binding of TNF to a TNF receptor and inhibit the cytotoxic effect of TNF, or a nucleotide sequence encoding a fragment of such a polypeptide which maintains the ability to interact with TNF. The invention further relates to expression vectors comprising such DNA molecules, host cells comprising such expression vectors, and methods of producing the polypeptide encoded by the DNA by culturing such host cells and recovering the polypeptide.

The examiner has required a more descriptive title.

The title has now been amended in order to satisfy this requirement.

The examiner states that claims 1 and 3-9 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 7-11, 14 and 15 of U.S. Patent No. 5,695,953. Furthermore,

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claims 8 and 9 have been rejected under the judicially created doctrine obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 5,811,261. The examiner states that a timely filed terminal disclaimer may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground.

Attached hereto is a terminal disclaimer disclaiming the term of any patent issuing from the present application that would extend beyond the term of the first to expire of U.S. Patent Nos. 5,695,953 and 5,811,261. Accordingly, this double patenting rejection has now been obviated.

Claim 2 has been rejected under 35 U.S.C. § 101 as claiming the same invention as that of claim 2 of prior U.S. Patent No. 5,695,953, as the genomic DNA or cDNA would inevitably encode the naturally occurring protein.

Claim 2 has now been deleted, thus obviating this rejection.

Claims 7-9 have been rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. The examiner states that claim 7 is incomplete because it depends on itself, and claims 8 and 9 are indefinite for failing to adequately point out what applicants see as the invention. The examiner suggests that the claims be amended to indicate the identity of the polypeptide being produced.

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Claim 7 has now been amended to correct its dependency so as to depend from claim 5, as had been originally intended. Claims 8 and 9 have now been amended in order to indicate the identity of the polypeptide being produced. Accordingly, it is believed that this rejection has now been obviated.

Claims 1-9 have been rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors had possession of the claimed invention. The examiner states that the specification only discloses a small portion of the polypeptide sequence, and no DNA sequence of any kind is identified or particularly described. This rejection is respectfully traversed.

The rejection in this case is substantially identical to the rejection that has been appealed to the Court of Appeals for the Federal Circuit with respect to a related case from the laboratory of the present inventors. The present application deals with DNA encoding TBP-I. The case that has been appealed to the Federal Circuit has claims directed to DNA encoding TBP-II. Otherwise, the issues are substantially identical. Attached hereto is a copy of appellant's main brief on appeal and reply brief in *In re*

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*Wallach*, Appeal No. 03-1328. This case was argued on April 8, 2004, and a decision could be forthcoming at any time. It is urged that the present rejection should be withdrawn for the same reasons as presented in the briefs before the Federal Circuit in *In re Wallach*.

Furthermore, it is requested that the examiner *sua sponte* suspend proceedings in this case pending issuance of a decision in *In re Wallach*, which should be dispositive of the issues presented in the present proceeding, one way or another.

Accordingly, for the reasons presented in the attached appeal briefs and for the reasons that are expected to be enunciated shortly by the Federal Circuit in its decision in Appeal No. 03-1328, the disclosure of a protein by partial amino acid sequence and sufficient other characterizing data to present a full written description of that protein, is sufficient to provide written description of the genus of DNA sequences which encode that protein. See also MPEP § 2163, at 2100-169, where it states:

For example, in the molecular biology arts, if an applicant disclosed an amino acid sequence, it would be unnecessary to provide an explicit disclosure of nucleic acid sequences that encoded the amino acid sequence. Since the genetic code is widely known, a disclosure of an amino acid sequence would provide sufficient information such that one would accept that an applicant was in possession of the full

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genus of nucleic acids encoding a given  
amino acid sequence, but not necessarily any  
particular species.

Reconsideration and withdrawal of this rejection are therefore  
respectfully urged.

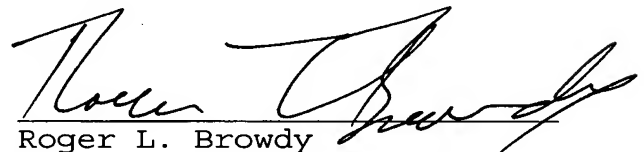
The prior art cited but not applied by the examiner  
has been noted, as has the examiner's implicit recognition  
that it is insufficiently pertinent to warrant its application  
against the claims.

It is submitted that all the claims now present in  
the case clearly define over the references of record and  
fully comply with 35 U.S.C. § 112. Reconsideration and  
allowance are therefore earnestly solicited.

Respectfully submitted,

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